



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: R.K. BAKSHI et al.

Serial No. 10/788,859

Filed: February 27, 2004

For: ACYLATED PIPERAZINE DERIVATIVES AS
MELANOCORTIN-4 RECEPTOR AGONISTS

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Barbel Brown Date 4/22/04

**INFORMATION DISCLOSURE STATEMENT**

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

Baerbel R. Brown

By: BAERBEL R. BROWN

Attorney _____ For Applicant(s)

Reg. No. 47,449

MERCK & CO., INC.

Patent Dept., RY60-30

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(732)594-0672

Date: 4/22/04

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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
			WO 03/009847		Amgem, Inc.	02/06/2003
			WO 01/58891		Vertex Pharmaceuticals Incorporated	08/16/2001
			WO 01/70708		Merck & Co., Inc.	09/27/2001
			WO 01/91752		Merck & Co., Inc.	12/06/2001
			WO 01/70337		Merck & Co., Inc.	09/27/2001
			WO 02/068388		Merck & Co., Inc.	09/06/2002
			WO 00/74679		Merck & Co., Inc.	12/14/2000
			WO 02/068387		Merck & Co., Inc.	09/06/2002
			WO 99/64002		Merck & Co., Inc.	12/16/1999
			WO 02/059095		Eli Lilly & Company	08/01/2002

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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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COMPLETE IF KNOWN

Application Number	10/788,859
Filing Date	February 27, 2004
First Named Inventor	RAMAN K. BAKSHI et al.
Group Art Unit	
Examiner Name	

Sheet	2	of	4	Attorney Docket Number	21291Y
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Examiner Initials*	Cite No.	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number Kind Code (if known)		
			WO 02/059107	Eli Lilly & Company	08/01/2002
			WO 02/059108	Eli Lilly & Company	08/01/2002
			WO 02/059117	Eli Lilly & Company	08/01/2002
			WO 03/007949	Merck & Co., Inc.	01/30/2003
			WO 02/070511	Bristol-Myers Squibb, Inc.	09/12/2002
			WO 03/093234	The Procter & Gamble Company	11/13/2003
			WO 03/094918	Neurocrine Biosciences, Inc.	11/20/2003
			WO 03/066597	Chiron Company	08/14/2003

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
			Application Number	10/788,859	
			Filing Date	February 27, 2004	
			First Named Inventor	RAMAN K. BAKSHI et al.	
			Group Art Unit		
			Examiner Name		
Sheet	3	of	4	Attorney Docket Number	21291Y

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Huszar et al., Cell, Vol. 88 (1997), pp. 131-141, "Targeted disruption of the melanocortin-4 receptor results in obesity in mice"
	AB	Dinsmore et al., Brit. Med. J., Vol. 318 (1999), pp. 387-390, "ABC of sexual health -- erectile dysfunction"
	AC	Kask et al., Biochem. & Biophys. Res. Comm., Vol. 245 (1998), pp. 90-93, "Selective antagonist for the melanocortin 4 receptor (HSO014) increases food intake in free-feeding rats"
	AD	Chen et al., Cell, Vol. 91 (1997), pp. 789-798, "Exocrine gland dysfunction in MC5-R-deficient mice ..."
	AE	Gingell et al., Exp. Opin. Ther. Patents, Vol. 9 (1999), pp. 1689-1696, "Emerging pharmacological therapies for erectile dysfunction"
	AF	Moreland et al., Life Sciences, Vol. 62, No. 20 (1998), pp. PL-309-318, "Sildenafil, A novel inhibitor of phosphodiesterase Type 5 in human corpus cavernosum smooth muscle cells"
	AG	Giraud et al., Brain Res. Vol. 809 (1998), pp. 302-306, "Feeding effects of hypothalamic injection of melanocortin 4 receptor ligands"
	AH	Graul, Drugs News & Perspectives, Vol. 9 (1996), pp. 572-575, "Latest findings on the diagnosis and treatment of erectile dysfunction"
	AI	Kopelman, Nature, Vol. 404 (2000), pp. 635-643, "Obesity as a medical problem"
	AJ	Hill et al., Science, Vol. 280 (1998), pp. 1371-1374, "Environmental contributions to the obesity epidemic"
	AK	Davidson et al., JAMA, Vol. 281 (1999), pp. 235-242, "Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat"
	AL	Guy Grand et al., Lancet, Vol. 2 (1989), pp. 1142-5, "Therapeutics: International trial of long-term dexfenfluramine in obesity "
	AM	Bray et al., Obesity Research, Vol. 7 (1999), pp. 189-98, "Sibutramine produces dose-related weight loss"
	AN	Yoram et al., Current Opinion in Urology, Vol. 7 (1997), pp. 349-353, "Oral pharmacotherapy in erectile dysfunction"
	AO	Heaton et al., Int'l J. of Impotence Res., Vol. 9 (1997), pp. 115-121, "A therapeutic taxonomy of treatments for erectile dysfunction: an evolutionary imperative"

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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Dorr et al., Life Sciences, Vol. 58, No. 20 (1996), pp. 1777-1784, "Evaluation of melanotan-II, a superpotent cyclic melanotropic peptide in a pilot phase-I clinical study"
	AQ	Wessells et al., Urology, Vol. 56 (2000), pp. 641-646, "Effect of an alpha-melanocyte stimulating hormone analog on penile erection and sexual desire in men with organic erectile dysfunction"
	AR	Douglas et al., Int. J. Obes. Vol. 7 (1983), pp. 591-595, "Plasma phentermine levels, weight loss and side-effects"
	AS	Ford et al., JAMA, Vol. 287(3) (2002), pp. 356-359, "Prevalence of the metabolic syndrome among US adults"
	AT	Wessells et al., J. of Urology, Vol. 160 (1998), pp. 389-393, "Synthetic melanotropic peptide initiates erections in men with psychogenic erectile dysfunction ..."
	AU	Corcos et al., Society for Neuroscience Abstracts, Vol. 23 (1997), Abstract No. 267.9, p. 673, "HP 228 is a potent agonist of melanocortin receptor 4, and significantly attenuates obesity and diabetes in Zucker fatty rats"
	AV	Peptides: Frontiers of Peptide Science, Proceedings of the 15th American Peptide Symposium, June 14-19, 1997, Nashville, TN

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